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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
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09/675,323

09/28/2000

Henry A. Lardy

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10/29/2004

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EXAMINER

PESELEV, ELLI

ART UNIT

PAPER NUMBER

1623

DATE MAILED: 10/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                                      |                                     |  |
|------------------------------|--------------------------------------|-------------------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>09/675,323 | <b>Applicant(s)</b><br>LARDY ET AL. |  |
|                              | <b>Examiner</b><br>Elli Peselev      | <b>Art Unit</b><br>1623             |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 07 September 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 33-39 and 56-69 is/are pending in the application.
- 4a) Of the above claim(s) 33-39 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 56-69 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

Claims 33-39 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on December 8, 2003.

Claims 56-69 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 56 is directed to the treatment of a androgen responsive disease comprising an administration of a steroid substituted by a large number of substituents and it would take an undue amount of experimentation to determine which specific compounds are effective against which specific diseases. Note, for example, there is a good reason to doubt that a compound wherein R5 is -NH-C(O)-C50 organic moiety, each of R7, R8, R12, R13, R14, R15, R16 and R17 represent an alkyl group of 50 carbon atoms substituted by proteins and R18 is a polymer such as nylon would have the same activity as a compound wherein each of R5, R7, R8, R12, R13, R14, R15, R16, R17 and R18 are hydrogens. Note that the terminology "optionally substituted" (claim 56) is not limited to any specific substituents but encompasses any chemical moiety such as proteins, polysaccharides, steroids etc. The term "polymer" encompasses such polymers as nylon, carbowax, neoprene, saran and poly(vinyl chloride) i.e. polymers which are not used for pharmaceutical purposes. The terms

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such as ether, thioether, an acyl group, a carbonate, a carbamate, alkyl, alkenyl and alkynyl are not limited to any number of carbon atoms and encompass moieties having 100 carbon atoms. Further, the terminology "androgen responsive disease" (claim 56) is not limited to any specific disease and it would take an undue amount of experimentation by a person having ordinary skill in the art to determine which specific diseases are androgen responsive.

Claims 57-69 are to the treatment of prostate cancer, benign prostatic hyperplasia, breast cancer, alopecia, acne, hypogonadism and hirsutism. However, no data has been presented showing the treatment of any diseases. Due to the highly unpredictable nature of treating the specific diseases encompassed by the claims and the difficulty of treatment the same, there is a good reason to doubt the effectiveness of the claimed methods based on the in vitro data presented in the specification on pages 77-81 relating to AR activity assay, anti-andiol activity, anti-DHT effects of steroids, suppression of the AED-induced AR transcriptional activity and steroid hormone specificity of DHEA metabolites presented. Applicant has not presented an evidence that such in vitro activity correlates with the treatment of specific diseases encompassed by the instant claims.

Applicant's response filed September 7, 2004 has been considered but has not been found persuasive.

The Miyamoto et al article has been considered but has not been found persuasive.

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The Miyamoto et al article shows that 3B-acetoxyandrost-1,5-diene-17-ethylene ketal functions as a potent antiandrogen with marginal agonist activity and that the antiandrogenic activities make ADEK a potential therapeutic agent. However, said reference fails to teach the treatment of any diseases but merely presents a speculative statement as to the potential treatment. Further, the compounds tested do not possess the substituents encompassed by the instant claims such as C50 organic moiety, a peptide, monosaccharide or oligosaccharide, which a person having ordinary skill in the art would expect to effect the activity of the compounds.

Claims 56-69 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are indefinite in that the variable Rpr (claim 56) has not been defined.

Claims 57-58 are substantial duplicates.

The claims are also indefinite in that claim 56 fails to state that the effective amount of formulation is administered to the subject in need of such treatment.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elli Peselev whose telephone number is (571) 272-0659. The examiner can normally be reached on 9.00-5.30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Wilson can be reached on (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Elli Peselev

*elli peselev*  
**ELLI PESELEV**  
**PRIMARY EXAMINER**  
**GROUP 1800**